Appendix 1: 510(k) Summary of Safety and Effectiveness

OCT 0 8 2002 K022565

Statement	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.
Device description	The *Telstar*™ Biplane Digital Imaging System [TIS] is a digital fluoroscopic system providing bi-plane fluoroscopic clinical images of both patients and medical devices during conventional and magnetic procedures.
Intended use	Provides the utility of fluoroscopic imaging of vascular systems for applications including vascular angiography and electrophysiology (EP) studies. This x-ray system may be used stand-alone, or in conjunction with an associated Stereotaxis Magnetic Navigation System.
Substantial equivalence	The TIS is a modification of the *Telstar*™ Biplane Digital Imaging System originally cleared under K013484. The modifications described herein do not affect the intended use of the device or alter the fundamental scientific technology associated with the device.
Technological characteristics	The TIS provides visualization through standard fluoroscopy.

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Appendix 1: 510(k) Summary of Safety and Effectiveness, Continued

Device comparisons – Imaging

The following clarifies the modifications to the Telstar Biplane Digital Imaging System cleared under K013484.

Device Characteristics	Current TIS (K013484)	Modified TIS
Imaging	Fluoroscopic	Fluoroscopic
Pulsed fluoro	7.5, 15, 30 pulses/sec	7.5, 15, 30 pulses/sec
Pulsed cardiac	15, 30 pulses/sec	15, 30 pulses/sec
X-ray tube assembly	Rotating anode	Rotating anode
Image intensifier	Yes	Yes
Monitor	Quad 15"	Quad 15"
Operating modes	Fast Scan Fluoro (2x2 binning) only	Fast Scan Fluoro and Low Noise, High Sensitivity Fluoro (2x4 binning)
Frame rate	Same	Same

Physical testing

The TIS is designed and tested in compliance with the requirements of 21 CFR §1020.32 (Fluoroscopic Equipment).

Preclinical animal performance data

Preclinical performance data were provided in K013484. No new studies were required or necessary to support the modifications.

Clinical performance data

Clinical performance data were provided in K013484. No new studies were required or necessary to support the modifications.

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Appendix 1: 510(k) Summary of Safety and Effectiveness, Continued

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Contact

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Director, Clinical & Regulatory Affairs
Stereotaxis, Inc.
4041 Forest Park Avenue
St. Louis, Missouri 63108
Ph. 314-615-6964
Fax 314-615-6912

Date

August 1, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Peter A. Takes, Ph.D., RAC
Director, Clinical &
Regulatory Affairs
Stereotaxis, Inc.
4041 Forest Park Avenue
ST. LOUIS MO 63108

Re: K022565
Trade/Device Name: Telstar Biplane Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Imaging-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: 90 MQB
Dated: September 6, 2002
Received: September 9, 2002

Dear Dr. Takes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix 2: Statement of Intended Use

Statement

Indications for Use Statement:

510(k) Number: K 022565

Device Name: Telstar™ Biplane Digital Imaging System [TIS]

Indications for Use: The Telstar™ Biplane Digital Imaging System provides the utility of fluoroscopic imaging of vascular systems for applications including vascular angiography and electrophysiology (EP) studies. This x-ray system may be used stand-alone, or in conjunction with an associated Stereotaxis Magnetic Navigation System.

Prescription Use ✓

David A. Seguin
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022565